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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/766,378	01/19/2001	Peter R. Rhode	48002-DIV (1758)	8910

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EXAMINER	
VANDERVEGT, FRANCOIS P	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/766,378	RHODE ET AL.	
	Examiner	Art Unit	
	F. Pierre VanderVegt	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-29 and 38-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-29,38-44 and 46* is/are rejected.

7)☒ Claim(s) *45 and 47* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application is a divisional of U.S. Application Serial Number 08/960,190.

Claims 1-24 and 30-37 have been canceled.

Claims 38-47 have been added.

Claims 25-29 and 38-47 are currently pending.

Election/Restrictions

1. Applicant's election without traverse of the species of the polyspecific MHC fusion molecule as depicted in Figure 9B of the specification in the Paper filed May 12, 2003 is acknowledged.

Applicant's election without traverse of the species of an immunoglobulin domain as the species for the joining molecule and CD3 as the species for the cell surface target in the Paper filed December 29, 2003 (copy refiled with postcard copy on February 9, 2004) is acknowledged.

Upon further review of the claims and specification, the species election requirement is hereby withdrawn.

2. In view of Applicant's amendment and the correction in inventorship filed January 21, 2003 no outstanding ground of rejection is maintained. The following represents a new ground of rejection and this Office Action is made NON-FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 25-29, 38-44 and 46 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "effector molecules" selected from the group consisting of antigenic peptides, specific cell toxins, receptor ligand, radionuclide, or a myc, 6xHIS or EE tag, does not reasonably provide enablement for the full range of molecules that qualify as "effector molecules" or for a "drug" as the effector molecule. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The claims are broadly drawn to encompass polyspecific MHC complexes comprising any of a number of molecules that may have any type of "effect" upon any cellular, biological or chemical moiety or function. The term "effector" has a broad meaning in the art and is used to denote any molecule that may have an effect upon another molecule or upon a process. Equally, the term "drug" also has a very broad meaning in the art, reasonably reading upon any substance that has any effect upon a subject. The nature of the claimed invention is that of an engineered molecule designed to exert an effect upon the cell-mediated and humoral immune response of a subject. However, the terms "effector molecule" and "drug" reasonably read upon substances that have no relationship whatsoever to the immune response. Accordingly, the instant specification does not disclose the full scope of effector molecules and the artisan would not be able to readily envision the range of effector molecules that could be included in the claimed complex without adequate guidance from the specification. The specification provides only a limited disclosure of effector molecules. For example, at page 15, lines 6-16, the specification discloses:

> "The term "effector molecule" as used herein in reference to a polyspecific MHC molecule of the invention refers to a molecule comprising an epitope capable of specifically binding an antibody (polyclonal, monoclonal or chimeric). Typically, the antibody will be a monoclonal antibody. The term is also meant to include a cell toxin, receptor ligand, drug, radionuclide, or a protein "tag" such as the well-known myc, 6xHIS or EE tags. Examplary tags have been disclosed in the published PCT Application Nos. WO 96/04314 and WO 97/28191. As will be more apparent from the disclosure that follows, in some cases a joining molecule can be an effector molecule (e.g., an Ig-C_L chain or fragment) as provided herein."

and at page 48, lines 4-23 in the passage:

> "As mentioned above, the MHC complexes of the present invention can include a variety of effector molecules. Suitable effector molecules include those which impart a desired biological, chemical or physical property to the MHC complex. More specifically, the effector molecule can be a cell toxin of, e.g., plant or bacterial origin such as, e.g., diphtheria toin (DT), shiga toxin, abrin, cholera toxin, ricin, saporin, pseudomonas exotoxin (PE), pokeweed antiviral protein, or gelonin. Biologically active fragments of such toxins are well known in the art and include, e.g., DT A chain and ricin A chain. Additionally, the toxin can be an agent active at the cell surface such as, e.g., phospholipase enzmes (e.g., phospholipase C). As another example, the effector molecule can be a chemotherapeutic drug such as, e.g., vindesine, vincristine, vinblastin, methotrexate, adriamycin, bleomycin, or cisplatin, or, additionally, the effector molecule can be a radionuclide such as, e.g., iodine-131, yttrium-90, rhenium-188 or bismuth-212. See e.g., Moskaug, et al. J. Biol. Chem. 264, 15709 (1989); Pastan, I. et al. Cell 47, 641, 1986; Pastan et al., Recombinant Toxins as Novel Therapeutic Agents, Ann. Rev. Biochem .61, 331, (1992); "Chimeric Toxins" Olsnes and Phil, Pharmac. Ther., 25:355 (1982); published PCT application no. WO 94/29350; published PCT application no. WO 94/04689; and U.S. Pat. 5,620,939, each reference hereby incorporated by reference)."

Beyond the effector molecules and chemotherapeutic drugs enumerated in the specification, the artisan would not be able to envision the full scope of "effector molecules" or "drugs" as encompassed by the claims and would therefore be required to engage in an undue amount of experimentation in order to make or use the claimed complexes of the invention.

In view of the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take undue trials and errors to practice the claimed invention and this is not sanctioned by the statute.

Conclusion

4. Claims 45 and 46 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00; Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D.
Patent Examiner
May 3, 2004

PATRICK J. NOLAN, PH.D.
PRIMARY EXAMINER
5/3/04